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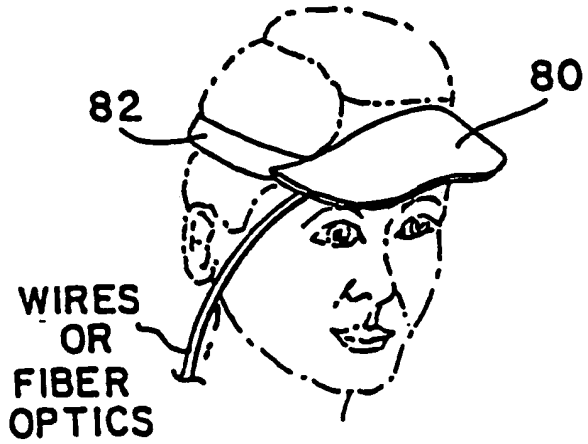

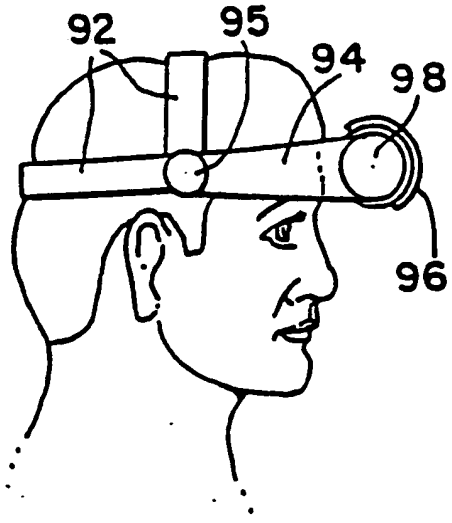

(57) Abstract

A method for delivering light to the eyes using a head mounted device (80) is described. The therapeutic benefit from this phototherapy was greater with lower intensities with a portable head mounted system as opposed to the very higher intensity bright lights used previously in conventional light therapy.

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LOW INTENSITY LIGHT VISOR FOR PHOTOTHERAPY

FIELD OF THE INVENTION

The present invention relates to certain improvements in phototherapy designed to alleviate the symptoms of seasonal affective disorders, such as winter depression or "blues"; other conditions of altered circadian rhythms, such as jet lag, shift work, premenstrual syndrome and delayed sleep phase syndrome.

BACKGROUND OF THE INVENTION

Phototherapy is a known effective treatment for winter depression and other psychological and psychiatric conditions. Considerable research in this area has been done over the years and numerous publications have been presented in the field.

It has been discovered that sunlight and bright artificial light can suppress human melatonin secretion; that patients with seasonal mood cycle winter depression improved when hours of daylight were lengthened with bright artificial light; that depression, hypersomnia, overeating and carbohydrate craving were reduced with phototherapy; that bright light has a marked antidepressant effect whereas dim light does not; that seasonal affective disorder (SAD) is reduced by phototherapy with the results of reduced irritability, reduced fatigue, reduced sadness and improved sleep; that exposure from 2 to 6 hours per day of light at 50 to 1000 lux reduces SAD and acts as an antidepressant; that phototherapy may aid in the treatment of bulimia and seasonal premenstrual syndrome.

Normal room light is insufficient, and even a brightly lit room is insufficient to have any phototherapeutic effect. Previously, phototherapy for the above conditions has been effected by large cumbersome light emitting boxes which are not easily portable and which are inconvenient. The patient is effectively fixed to the equipment and cannot proceed with other activities. As phototherapy must be carried out for at least one hour per day, and preferably at least two to four hours per day

to be effective, prior light emitting boxes have proven very inconvenient for the patient.

A large body of prior art exists which, while not directly pertinent to the treatment of SAD and related disorders, is of background interest for reasons which will be apparent below. Thus, miners' lamps are known which comprise a head mounted torch or flashlight for working in dark locales. In devices of this type, of course, the light is directed away from the eye rather than toward it.

The U.S. patent to Wyatt USP 4,360,253 relates to a safety glass mounted test result indicator including a small light emitting diode mounted on a spectacle frame. Of course, the degree of light provided by such an LED is far too low to be effective for the treatment of SAD, and also the light provided is not a steady beam of light for any significant length of time. Also see the U.S. patents to Rinard et al USP 4,145,122; Scrivo et al USP 4,086,004; Hamilton et al USP 4,044,756; and Harding et al USP 3,621,836, all of which are also unsuitable for the treatment of SAD and related disorders for reasons similar to those pointed out above.

The U.S. patents to Giannone USP 4,057,054 and Rehm USP 3,883,225 relate to eye treatment devices incorporated into or onto spectacle-like frames. These also are unsuitable for the treatment of SAD not only because of the absence of providing a steady beam of light at a sufficient intensity for a sufficient period of time, but also because such devices suffer from the same defects as the light boxes, i.e. they do not permit the patient to proceed with other activities during the treatment.

Lastly, attention is invited to a letter to the editor appearing in Vol. 43 (Feb. 1986) Arch. Gen. Psychiatry by Mueller and Davies. In this letter, the authors suggest treatment of SAD (referred to as seasonal energy syndrome) by the utilization of red-spectrum light in the fall-winter period as being superior to and more practical than full spectrum light, and this is suitable

achieved by the use of rose colored glasses. The use of spectacle frames or the like as a supporting means for light projecting means for directing a steady stream of light into the eye of the patient is not suggested.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a schematic overall view of one possible embodiment of the device used to administer the light intensities of the present invention;

Fig. 2 is a schematic view of a second embodiment for the device;

Fig. 3 is a more detailed, enlarged view consistent with, for example, the embodiment of Fig. 1;

Fig. 4 is a schematic perspective view of a detail consistent with the embodiment of Fig. 2;

Fig. 5 is a top view of a user's head wearing eyeglass frames consistent with the embodiment of Fig. 1;

Fig. 6 is an enlarged schematic front view of one eye showing various possibilities;

Figs. 7A, 7B and 7C are enlarged schematic views from above showing various possible arrangements in accordance with the invention;

Fig. 8 is a schematic perspective view showing another mounting means which can be used in accordance with the present invention;

Fig. 9A is a schematic perspective view showing yet another embodiment in accordance with the present invention;

Fig. 9B is a schematic side view of the device of Fig. 9A;

Fig. 10 depicts test results using light visors at the light intensities of the present invention.

SUMMARY OF THE INVENTION

It is, accordingly, an object of the present invention to overcome deficiencies in the prior art, such as indicated above.

It is another object of the invention to provide for the more convenient treatment of SAD and related disorders.

It is still another object of the present invention to administer light in a convenient and portable way to individuals with winter depression, the "winter blues" and other light responsive psychological and psychiatric conditions, as well as to enhance immune function.

It is a further object to provide a device for shining light into an eye of a patient for the treatment of depression or the like.

It is still a further object of the invention to provide for the use of a head mounted lamp in the alleviation of sleep problems, depression, jet lag, winter blues, and to affect changes in the lymphocytes so as to affect the functional immune system.

One of the major problems in administering light therapy is the inconvenience of having to be close to a cumbersome and heavy light fixture. There were no small portable fixtures being used for phototherapy. Although a device involving a few incandescent plant lights has been recommend for the treatment of SAD, there have been no previous reports of devices which are portable and worn or placed close to the eyes.

Devices for administering the light intensities of the present invention are manufactured much less expensively than the prior light emitting boxes, because of the much smaller size and the smaller amount of light needed in view of its source being closer to the eyes. Small size involves not merely a reduction in size by downscaling, but provides the added advantages of being mounted on the user's head rather than resting on a nearby table or the like, thus ensuring that the light source is a fixed distance from the eyes and the flux to the eyes will be consistent.

Devices for administering the light intensities of the present invention mount a suitable light source of sufficient power and are capable of shining a steady beam of light into the user's eyes for a sufficient time, mounted a headband, hat or helmet-like support, with the light being directed toward the user's eyes to provide a

therapeutic dosage of light.

The devices provide for an improved light delivery system, which desirably utilizes a high intensity halogen or other incandescent bulb as well as means for directing a large fraction of the light from the bulb directly into the patient's eye, without focusing the light in a way that could cause damage to the eye or to the patient. By the proper selection of such a light directing means, including an appropriate means for focusing the beam of light in front of the patient's eye such as a positive or convex lens, preferably of the Fresnel type, the light appears to the patient to be coming from an area much larger than the actual point source, and hence is more comfortable to use. The patient is assured of receiving a significant dosage of light no matter which way he is directing his gaze.

The light-emitting element may also consist of a fluorescent bulb as exemplified in more detail below. Because the intensity of light incident on a surface is inversely proportional to the square of the distance from that surface, it follows that a light source close to the eye (e.g. at most a few inches away) needs to be considerably less powerful than a light source which is some distance away. Thus, when the light source is mounted on the head of the patient, the amount of light required to be emitted from the source needs only to be many times less intense than that required for equal phototherapy from a conventional light box placed at a distance approximately three feet from the patient.

The placement of the fluorescent bulb is important. In all cases it is important that the user's vision not be obstructed, particularly in the forward looking direction. On the other hand, it is also important that the power source and light source, functioning as light generating means, serve to generate a steady beam of light, preferably white or yellow light, at an intensity of at least 50 lux, preferably at least 400 lux, and that the power source be capable of maintaining such a steady

beam of light for a period of at least about 0.5 hours, and preferably at least two hours per day, it being further understood that when the intensity is minimal, i.e. about 50 lux, the term during which the steady light beam is applied must be maximal.

As indicated above, the phototherapy delivering system has considerable advantages over the previous devices used for delivering phototherapy, particularly in portability, convenience and patient comfort. The means for delivery of light to the eyes and the support means as disclosed are very convenient, simple, inexpensive and effective. The overall system is capable of delivering 50 to 10,000 lux of steady light to the patient's eyes for five hours to about 30 minutes per day, which is important, as is that such delivery of light be in a convenient and portable manner so that the patient can go about other business, and that the delivery be in a way which is not unpleasant to the patient.

The use of such a head mounted light source, preferably a fluorescent lamp, serves the purpose of alleviating and preventing a variety of psychological and physical conditions, including winter depression or SAD, a mild version of this condition known as "winter blues", premenstrual syndrome, jet lag, the physical and psychological discomfort associated with shift work, certain disorders of circadian rhythms such as delayed sleep phase syndrome, and certain infectious and inflammatory conditions which call for modulation of the immune system.

The nature of the device used to administer the light intensities of the instant invention will be more apparent from the following detailed description of several embodiments, taken in conjunction with the drawings wherein:

Fig. 1 shows a first construction for a device to administer the light intensities of the present invention including spectacles 10 which may or may not have lenses. A power source 12 and light source 14, similar to a standard battery operated flashlight, is worn on the

user's belt. A fiber optic bundle 16 carries the light generated by the light source, which may be one or more light bulbs or a fluorescent bulb or the like, to the spectacles 10. On the front of the spectacle frames are provided diffusing and/or reflecting elements 18 which direct the light in a comfortable pattern towards the user's eyes.

The power source 12 may optionally include a battery charger and/or a plug connection 20 and line cord for obtaining power from the mains, to replace and/or supplement the battery pack.

The placement of the diffusing and/or reflecting elements 18 is important and is described in more detail below in conjunction with Figs. 3-7. In all cases it is important that the user's vision not be obstructed, particularly in the forward looking direction. On the other hand, it is also important that the power source and the light source, functioning as light generating means, serve to generate a steady beam of light, preferably white light, at an intensity of at least 50 lux, preferably at least 400 lux, and that the power source be capable of maintaining such a steady beam of light for a period of at least about 0.5 hours, and preferably at least two hours per day, it being further understood that when the intensity is minimal, i.e., about 50 lux, the term during which the steady light beam is applied must be maximal, i.e., about five hours in length.

Another important factor is the positioning of the light projecting means, and this is important for a number of reasons. First, as already mentioned above, intensity is inversely proportional to the square of the distance of the eye from the source, and therefore the light projecting means, i.e., the diffusing or reflecting means 18, should be located as close to the eye as possible. On the other hand, the comfort of the patient is of considerable importance, and therefore the beam of light should be projected in a direction which provides the greatest comfort for the patient. As this may vary from patient

to patient, it is desirable that suitable means for adjusting the distance and angle of the light projecting means be provided. For this same reason, it is also desirable to provide means for adjusting the intensity of the light.

Fig. 3 shows a number of possibilities for placement of diffusers or reflectors which may be used in conjunction with the embodiment of Fig. 1. The fiber bundle 16 is shown arriving at the spectacles frame at the rear, and splitting to serve an array of diffusing and/or reflecting elements disposed around the perimeter of the lenses as illustrated by positions A, B, C and D. For some patients it may be desirable to have diffusers or reflectors at plural positions, while for other patients one position may be sufficient.

Fig. 5 shows one example where the fiber bundle 16 splits behind the patient's head and where individual fibers 162, 164 and 166 terminate closely adjacent mirrors 163, 165 and 167, respectively, which reflect the beams of light exiting from the fiber ends toward the eye of the patient. Preferably the mirrors 163, 165 and 167 are diffuse reflective surfaces. Refractive elements can also be used.

Fig. 2 shows an alternative embodiment 40 in which the power source 42 is still worn on the belt or provided with a line cord. In this embodiment 40, however, the light source, which itself acts as the light projecting means, are light bulbs 48 mounted directly on the eyeglass frames, the electrical power passing through the suitable wires 45.

The embodiment 40 of Fig. 2 also shows the use of an optional timer 50 and an optional transformer or rheostat 52 for adjusting power for control of light intensity. It will also be understood that a suitable timer 50 and/or a means 52 for adjusting the intensity of the beam of light can be used in any other embodiment, such as the embodiment 10 of Fig. 1.

Fig. 4 shows spectacle frames having light bulbs

48 powered through the wires 45 consistent with the embodiment of Fig. 2. Of course, the light bulbs 48 may be placed in any desirable configuration which is most comfortable for the user, yet which will provide to the eyes a steady beam of light at an intensity of at least 50 to 1000 lux for a period of from five hours to about 30 minutes.

Fig. 6, which is a front view of an arrangement consistent with that shown in Fig. 3, illustrates a desired arrangement wherein the patient's forward viewing is not obstructed, but at most only peripheral vision. The various light projecting elements A, B, C and/or D may be diffusers, reflectors, refractors or actual light sources such as the light bulbs 48 of Fig. 4.

Fig. 7A shows a fiber bundle 16A having its end projecting a light beam against a reflector 18A which reflects the beam toward the eye. The reflector 18A is preferably adjustably mounted so that it can be moved toward and away from the eye and the end of the fiber and/or so that it can be rotated to adjust the angle at which the beam is reflected toward the eye.

Fig. 7B alternatively shows a refractively terminated fiber optic or naked fiber 16B having its end shaped so that the beam of light passed therethrough will strike the eye at a suitably effective, yet comfortable, angle. Means for adjusting the angle or distance from the eye of the end of the fiber is also preferably provided.

Fig. 7C schematically shows wires 45C leading to a bulb 48C for projecting a beam of light to the eye. In this case, an optional optical element 47 may be provided in the form of a screen, lens, reflector or parabolic mirror or the like.

Fig. 8 provides a schematic representation of a mounting or supporting means over other than spectacle frames. Here a hat or cap bill, brim, or visor 80 is provided on which is mounted the light projecting means, e.g., a suitable fiber optic system as described above, or the combination light projecting means and light

generating means, e.g., one or more light bulbs either alone or with optional optical elements such as a screen, lens, reflector or parabolic mirror or the like, also as described above. The bill, brim or visor 80 may be itself supported by a band 82 or made from part of a cap or hat. The bottom side of the visor or bill 80 may be reflective. The mounting arrangement of Fig. 8 gives a reasonably physiological orientation of delivered light, because the light comes from above as from the sun or sky.

Fig. 9A and 9B show another variation having a support means similar in nature to that provided by a welder's mask or glasses, and including a pair of supporting adjustable head bands 92 and pair of adjustable visor arms 94 connected to the head bands 92 by suitable pivot connections 95 so that the visor arms can be rotated upwardly and downwardly in an arc about the pivot 95. The distal ends of the adjustable visor arms 94 in turn support a casing 96, preferably formed of plastic, and preferably provided with an internal reflector and housing therewithin a fluorescent bulb 98 which projects light downwardly toward the eyes.

As indicated above, the phototherapy delivery system of the present invention has considerable advantages over the previous devices used for delivering phototherapy, particularly in portability, convenience and patient comfort. The precise means for delivery of light to the eyes and the precise support means are not critical, but what is very important is that the overall system be capable of delivering 50 to 1000 lux of steady light to the patient's eyes for five hours to about 30 minutes per day, that such delivery of light be in a convenient and portable manner so that the patient can go about other business, and that the delivery be in a way which is not unpleasant to the patient.

Figures 10A-D compare the percentages of patients responding to phototherapy with light visors of either 400 lux or 7000 lux and when using light boxes of bright (2500 lux or more) or dim (300 lux or less) intensities. The

light visor data were derived from recent studies in which the inventors on this patent application were involved. The light box data were derived from earlier studies performed by various investigators in the field (Reviewed in Reference #4). The dark areas represent the percentage of patients responding to that particular phototherapy treatment, as determined by standardized response criteria, which have been previously established.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Traditionally, a patient has been treated by staring at very bright lights of 2500 lux or more, and current thinking has it that the greater the intensity and duration, the greater effect (see references 1-5). Lower lighting intensities of approximately 300 Lux have been shown not to be therapeutic in alleviating the symptoms of seasonal affective disorder.

Applicants have discovered that low levels of light previously proven to be ineffective when administered by a light box are nonetheless highly effective when the light is administered by a light visor worn by the patient. It has been found that light intensities of about 400 lux are sufficient to provide effective therapy when administered by a light visor, and we believe that light intensities of a wide range (50 to 1000 lux) will also be sufficient for this therapeutic effect. These levels are much lower than previously reported to be necessary for the antidepressant effect in seasonal affective disorders. This effect of lower levels of light would not have been predicted on the basis of previous work, which suggested that such lower levels were ineffective. The reason for the antidepressant efficacy of low intensity light is unclear at the present time as this discovery contradicts earlier work (references 1-5). Applicants do not wish to be bound by any particular theory; however, it is believed that the efficacy derives predominantly from the light delivery system as opposed to the specific type of disorder being treated.

The preferred duration of phototherapy and the

preferred intensity can vary from subject to subject depending on the individual, the severity of the disorder and the amount of light the subject normally receives outside of the phototherapy treatments. While thirty minute and one hour treatments were the standards used, treatments of significantly shorter and longer exposures may be appropriate. The preferred intensity and duration for any particular individual would be easily determined by those skilled in the art.

A variety of light visor designs may be used such as those previously described. All of these have three preferable features in common: they are portable, held close to the eyes in a fixed position and preferably shine light peripherally into the eyes so as not to completely obscure the field of view. The light may be provided directly by one or more lamps or indirectly by optical fibers to one or more locations and shining light into the eyes at one or more angles.

The reduced level of light needed has several advantages over the very bright levels previously believed to be critical for the effect. First, by reducing the level of light to the eyes, any change of eye damage, which would be more likely to occur with very bright lights would be minimized. Second, by using lower intensities, the heat produced would also be lower and thereby thermal damage would be minimized. Third, at a lower intensity a portable energy source may be lighter or smaller and/or last longer for the convenience of the wearer. Fourth, the glare would be reduced and interference with other activities of the user and other people and items nearby would be minimized.

Furthermore, the use of lower light intensities has been found to be more effective than very bright lights. This result is independent of the duration of light exposure.

Portable head-mounted light visors were tested in 55 patients with seasonal affective disorder. The visors deliver reflected, diffused light from two halogen lamps

2.5 inches from the eyes. Bright and dim light visors of 7,000 lux and 400 lux respectively were tested at three locations on opposite ends of the country. Two separate parallel design studies in separate patient groups using either one hour or thirty minutes of morning light were conducted at these locations. The most stringent remission criteria of Terman et al. (HDRS<8 and >50% HDRS score reduction) were used to assess outcome with Fisher's Exact Test, see Fig. 10.

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36. Rosenthal NE, Genhart MJ, Sack DA, Skwerer RG, Wehr TA. Seasonal affective disorder and its relevance for the understanding and treatment of bulimia. In: The Psychobiology of Bulimia. Hudson JI, Pope HG, Jr. (eds), American Psychiatric Press, Washington, D.C.

37. Kasper S. Rosenthal NE. Anxiety and depression in seasonal affective and the therapeutic effects of light. In: Anxiety and Depression: Distinctive and Overlapping Features. Kendall PC, Watson D (eds), Academic Press, Inc., Orlano.

38. Kasper S, Rogers S, Yancy A, Skwerer RG, Schulz PM, Rosenthal NE (1987): Psychological effects of light therapy in normals. *Seasonal Affective Disorder and Phototherapy*, In Press.

31. Skwerer RG, Rosenthal NE, Fleisher TA, Wehr TA, Mghir R, Paciotti GF, Tamarkin L. Eye-exposure to bright white light modulates lymphocyte blastogenesis in humans and rats. Submitted for publication.

It will be obvious to those skilled in the art that various changes may be made without departing from the scope of the invention. The invention is not to be considered limited to what is shown in the drawings and described in the specification, but only by the scope of the following claims.

WHAT IS CLAIMED IS:

1. A method for providing phototherapy to a subject comprising mounting a light source on the head of the subject, and providing light sufficient to reach the eyes at an intensity between about 50 to about 1,000 lux.

2. The method of claim 1 whereby the light is shined into the peripheral vision of the eyes and does not block the primary vision of the subject.

3. The method of claim 1 whereby the light source is a steadily shining beam of light directed into the eyes.

4. The method of claim 1 wherein the light intensity is about 400 lux.

5. The method of claim 1 wherein the light source is mounted on the head of the subject in a fixed relationship to the eyes.

6. Use of a light source mounted on the head of a subject which provides a light source sufficient to reach the eyes of the subject at an intensity between about 50 to about 1000 lux as phototherapy for the treatment of seasonal affective disorder (SAD), bulimia and seasonal premenstrual syndrome.

FIG. 1.

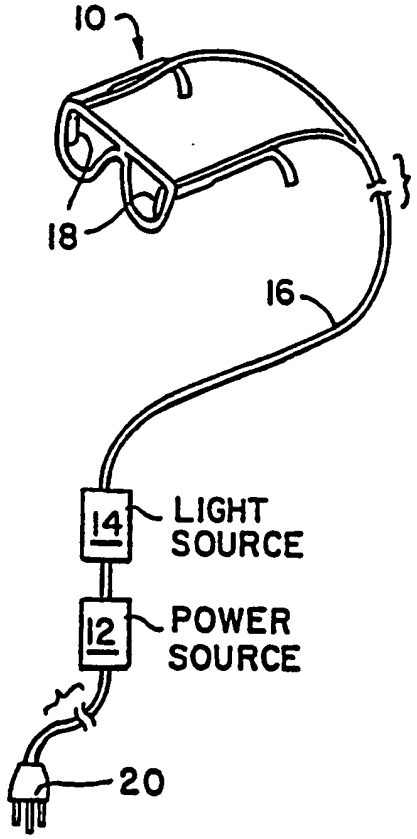


FIG. 2.

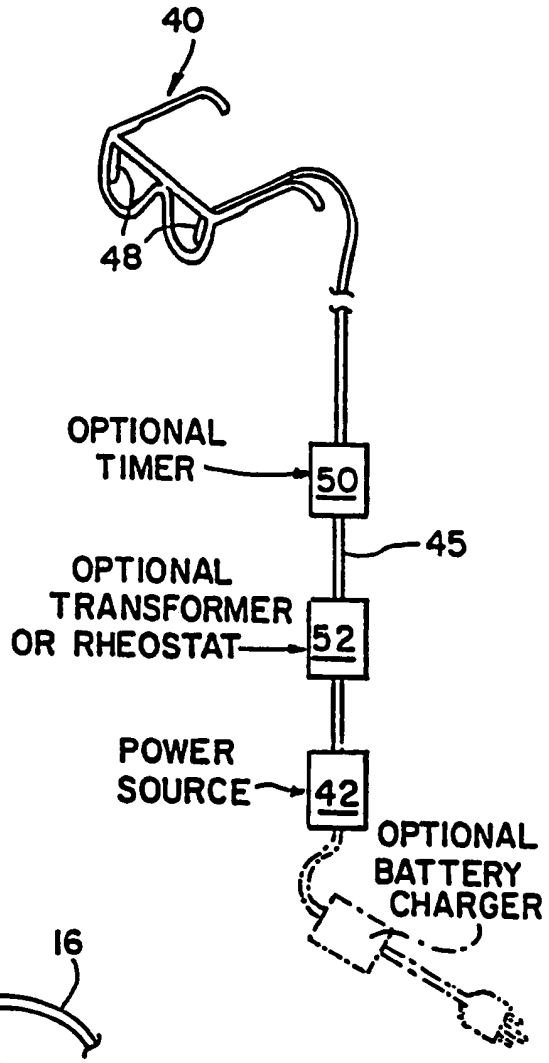


FIG. 3.

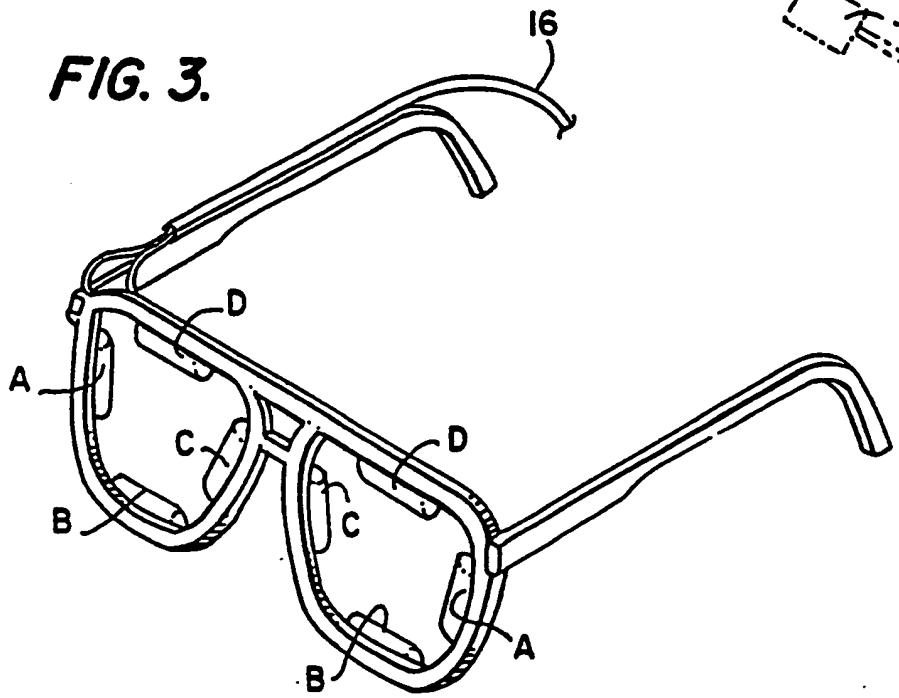


FIG. 4.

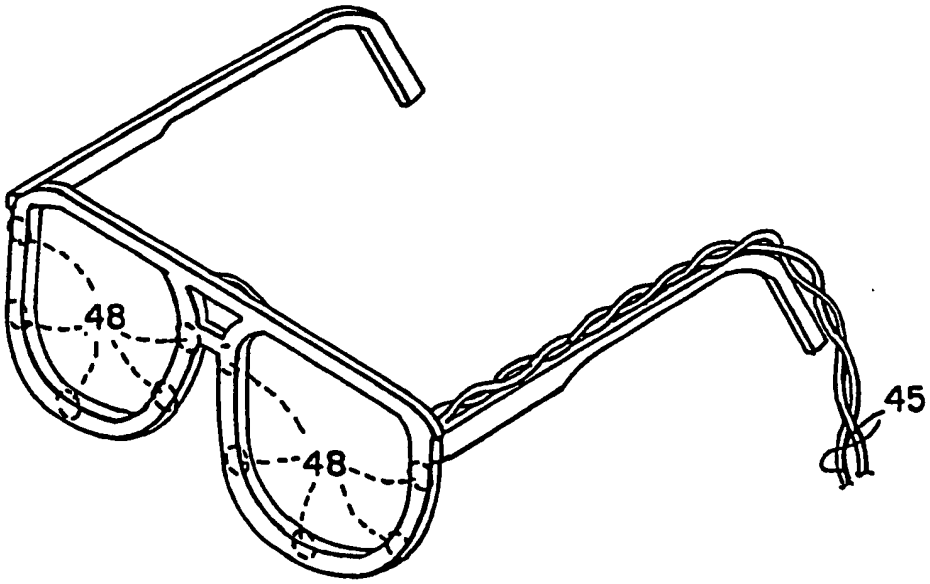


FIG. 5.

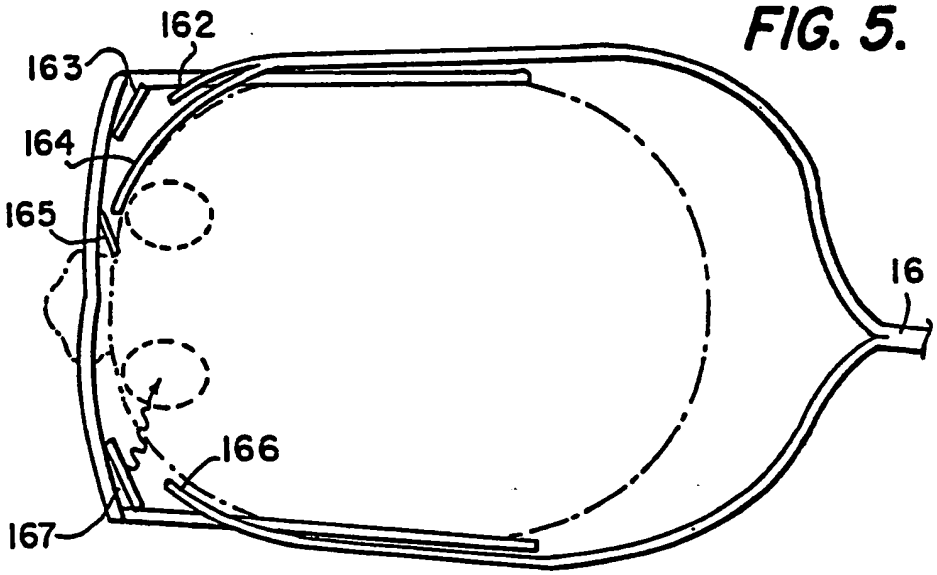


FIG. 6.

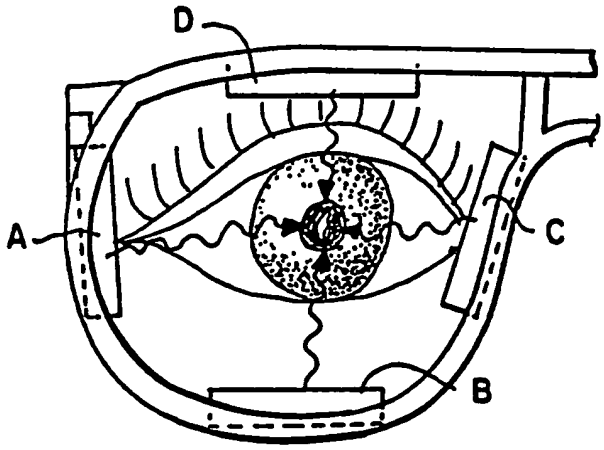


FIG. 7A.

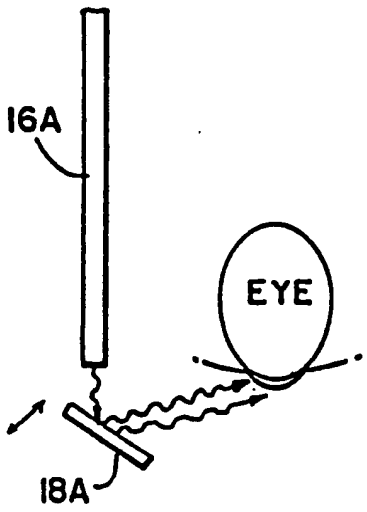


FIG. 7B.

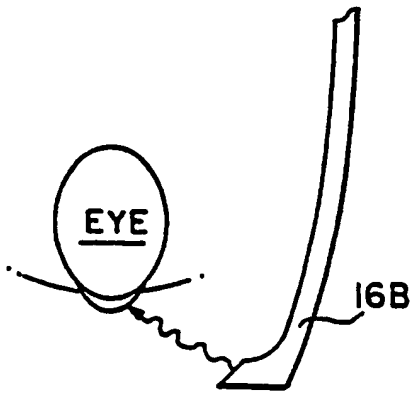


FIG. 8.

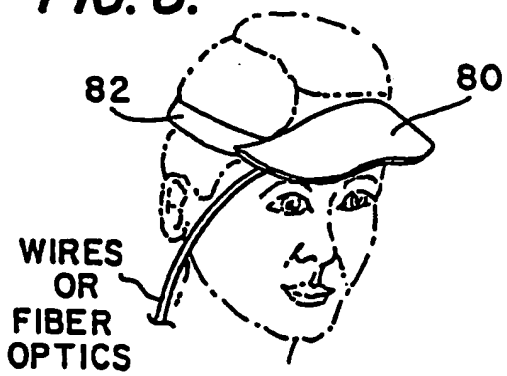


FIG. 7C.

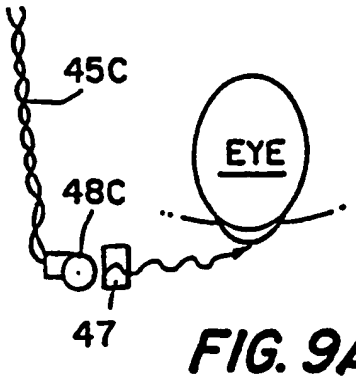


FIG. 9A.

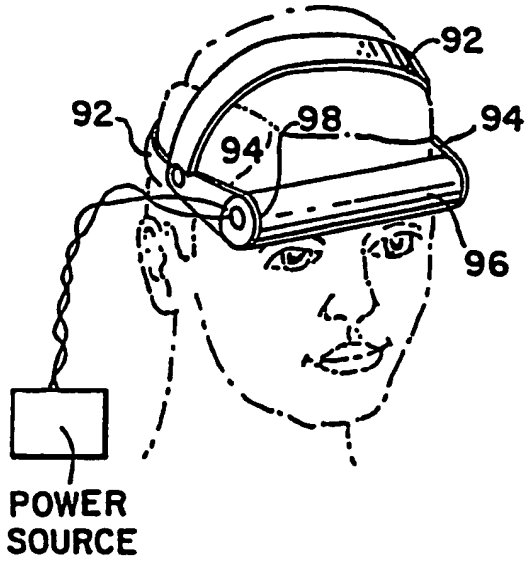
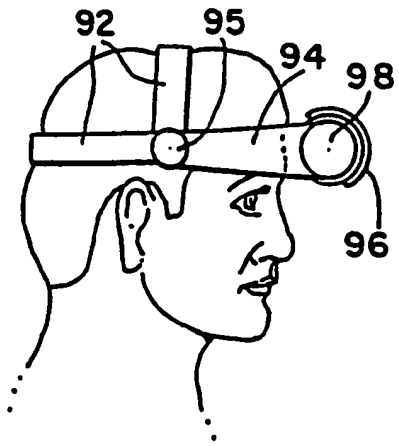


FIG. 9B.



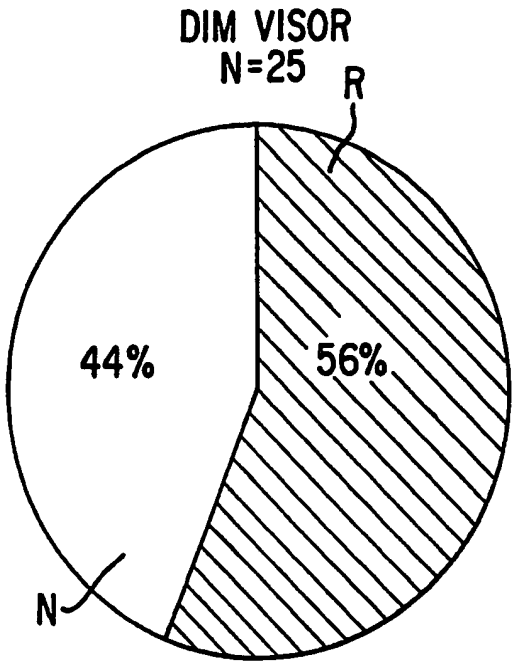


FIG. 10A

P=0.03

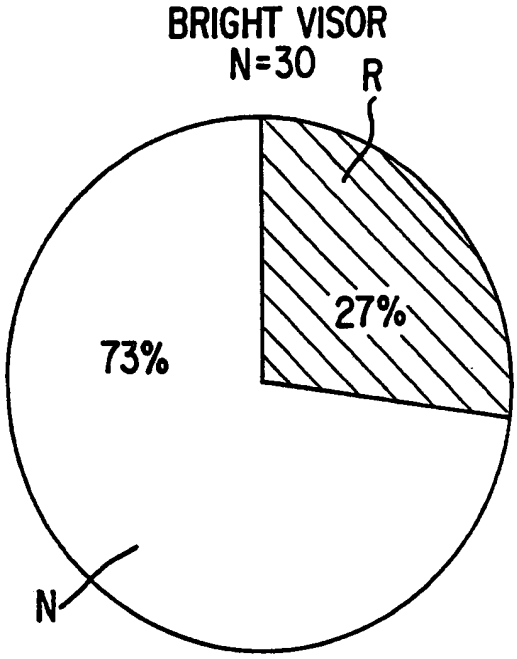


FIG. 10B

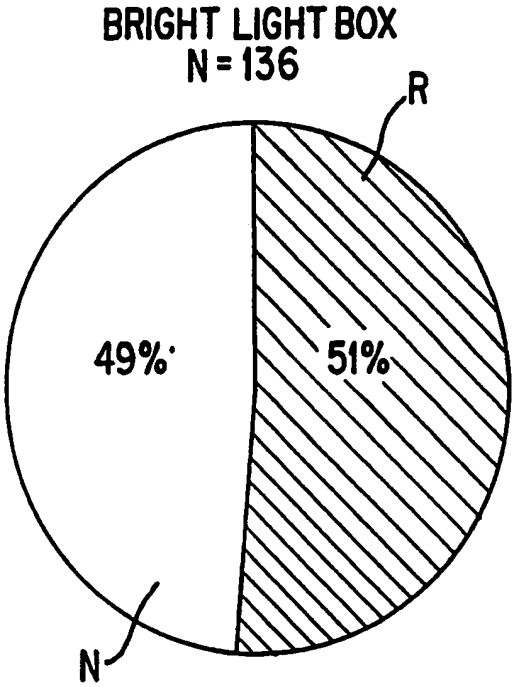


FIG. 10C

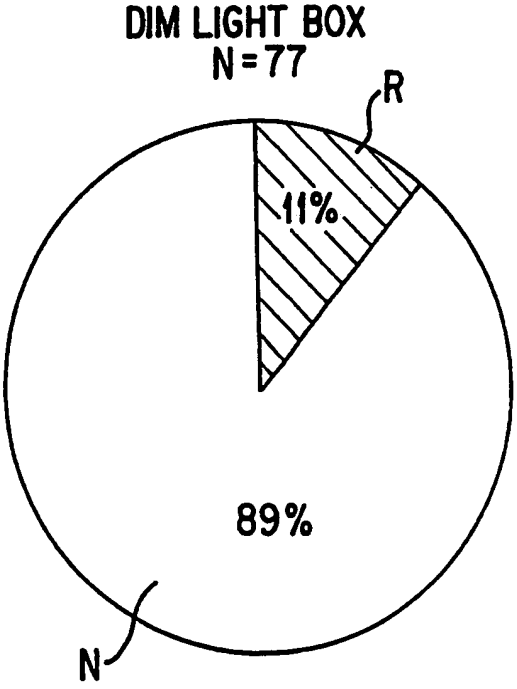


FIG. 10D

INTERNATIONAL SEARCH REPORT

International Application No. PCT/US91/01964

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [6]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC(5) A61N 5/00
US. Cl. 128/395

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
U.S.	128/24.1,380,395-398,791,793 351/158,203,213

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category *	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
Y	US, A, 3,621,838 (HARDING et al.) 23 November 1971 See column 2,3.	1-6
Y	Acta. Psychiatr. Scand. 1986:74:193-204 (WIRZ-JUSTIKE et al.) "Light Treatement of Seasonal Affective Disorder in Switzerland"	1-6

* Special categories of cited documents: [10]

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the prionty date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
10 May 1991	28 JUN 1991
International Searching Authority	**Signature of Authorized Officer**
ISA/US	For Mark S. Graham Ngocho Nguyen NGUYEN NGOC-HO INTERNATIONAL DIVISION

Form PCT/ISA/210 (second sheet) (Rev.11-87)